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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,961	07/11/2000	A. Bart Flick	60200.0022USI1	1541

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EXAMINER	
LEWIS, KIM M	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 06/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/613,961	FLICK, A. BART	
	Examiner	Art Unit	
	Kim M. Lewis	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-19,23,26-32 and 34-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *23,26-32 and 34-36* is/are allowed.

6)☒ Claim(s) *1,3,4 and 6-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ■ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/23/06 &3/26/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*.

DETAILED ACTION

1. This office action is in response to the Decision Granting Petition under 37 CFR 1.313, mailed 3/8/06. Accordingly, the application has been withdrawn from issue for consideration of a submission under 37 CFR 1.114 (RCE).

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 2/23/06 has been entered.

Information Disclosure Statement

3. The information disclosure statements filed 2/23/06 and 3/26/06 have been received and made of record. Note the acknowledged PTO-1449 forms enclosed herewith.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact

> terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. More specifically, the recitations that "the tubular shape is incorporated into a wound drain" (claim 14) or "a medical device.... and an appliance, wherein the wound dressing is incorporated into the appliance" (claim 15) is not described in the specification. The specification provides enablement for the dressing to be used as a wound drain, not incorporated into wound drain or an appliance.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As regards claim 13, "the device" lacks antecedent basis. The phrase should read --the wound dressing--.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1, 3, 4, 6-13 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Electric Silver Antisepsis ("Marino et al.")

As regards claims 1,3 and 4, Marino et al. substantially disclose applicant's presently claimed invention. More specifically, Marino et al. disclose a wound dressing that is capable of treating a pathology in a portion of a living organism, comprising at least one layer of conductive fabric having a surface resistance of less than about 1000 Ohms/cm^2, a biologically inert polymer (nylon) uniformly coated with a metal or metal alloy (silver), and wherein the wound dressing is ***capable*** of passively lowering the pathology's electrical potential by and mount effective to promote healing (note col. 1, 3rd para.-col. 2, 1st para. of Marino et al. and the definition of surface resisitvity provided in the Declaration of David Marx filed 2/22/05).

Marino et al. fail to teach that the dressing is conformable. However, given the environment in which the dressing is used one having ordinary skill in the art would have been motivated to make the dressing of Marino et al. conformable to a wound in order to better fit the wound, thereby causing less trauma thereto.

As regards claims 6 and 7, Marino et al. fail to teach that the wound dressing is an orthotic appliance or a dental appliance. However, Marino et al. recite in col. 2, 4th para. that the wound dressing is for the treatment of soft-tissue infections. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the wound dressing of Marino et al. to infected gums or to a decubitis ulcer on the heel of a patient, thereby being a dental appliance or an orthotic device, since Marino et al. state that the wound dressing is for treatment of soft-tissue infections.

As regards claims 8-12, the "recitations shaped for use around ostomy sites", "shaped for use around tracheostomy sites", "shaped for use around catheter sites" and "shaped for packing body cavities" do provide definitive structural limitations. Thus, the office takes the position that the wound dressing of Marino et al. is ***capable*** of the claimed functions of use around an ostomy site, use around a tracheostomy site, use around a catheter site and for packing a body cavity and therefore must be "shaped" as such.

As regards claim 13, Marino et al. fail to teach that the wound dressing has a tubular shape. Absent a critical teaching and/or showing of unexpected results derived from the tubular shape of the wound dressing of the instant invention, the examiner

contends that the shape of the dressing is an obvious design choice, which does not patentably distinguish applicant's invention. Therefore, it would have been an obvious design choice to one having ordinary skill in the art to modify the shape of the wound dressing of Marino et al. as an obvious design choice to fit different shaped wounds.

As regards claim 19, Marino et al. substantially disclose applicant's presently claimed invention. More specifically, Marino et al. disclose a wound dressing that is for the treatment of soft-tissue infections and prevention of burn-wound sepsis (col. 2, para. 3). It is inherent that the wound dressing is applied to a pathology of a portions of a living organism. The wound dressing comprises at least one layer of conductive fabric having a surface resistance of less than about 1000 Ohms/cm^2, a biologically inert polymer (nylon) uniformly coated with a metal or metal alloy (silver), and wherein the wound dressing is ***capable*** of passively lowering he pathology's electrical potential by and mount effective to promote healing (note col. 1, 3rd para.-col. 2, 1st para. of Marino et al. and the definition of surface resistivity provided in the Declaration of David Marx filed 2/22/05).

As can be clearly read from the article, there is no use of an external energy source or galvanic cell action.

As regards altering the electrodynamic process of a portion of the body, silver and other antimicrobial metals inherently possess the property of altering an electrodynamic process of a portion of the body in which they contact, specifically the portion of the body containing wound exudates. This is a natural occurrence since wound fluid contains electrolytes, thereby being electrically conductive. Applicant

should note that when the metallic material is placed in contact with wound fluid, an electrochemical reaction takes place, and depending upon the amount of metallic material that is introduced into the wound, an antimicrobial or analgesic effect occurs. Such effect is produced through an alteration/shift in the electrical potential of the wound fluid in and around the wound site.

It is deemed that the pathology's electrical potential of the would necessarily be lowered as an intrinsic consequence of the placement of the wound dressing of Marino et al. within the user's body since the instant invention employs the same conductive material.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 15-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-18 respectively of copending Application No. 11/119354 ("the '354 application"). Although the conflicting claims are not identical, they are not patentably distinct from each other because the same structural and functional limitations are present in both claims 15-18 of the present invention and of claims 15-18 of the '354 application. The only difference is the arrangement of the wording.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

13. Claims 23, 26-32, 34-36 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Mon., Wed., and Fri., from 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett, can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000

Kim M. Lewis
Primary Examiner
Art Unit 3743

kml
May 29, 2006